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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/734,787

12/13/2000

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END-712

6087

7590 03/23/2010
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

03/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/734,787	Applicant(s) RITCHART ET AL.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18, 21, 22 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) 36-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 36 – 39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 36 – 39 are directed to Embodiments disclosed in Figures 1 – 24. Claims 17, 18, 21 and 22 are directed to an Embodiment disclosed in Figures 31 - 34. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36 – 39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

It is noted that Page 27, lines 5 – 6 of the specification state “This embodiment, as well, may be adapted for use with the device illustrated in Fig. 1.” However, the specification does not address how the Embodiment of Figures 31 – 34 which extends from the open distal end of outer needle in order to expand could be used with the closed tip embodiment of Figure 1. Also, the specification fails to address how the hooked extractors of Figures 31 – 34 could be used with a tissue stop in that the hooked extractors would keep the sample from being released once engaged with the tissue stop.

Accordingly, claims 36 – 39 are not supported by the Embodiment described in Figures 36 – 39.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,198,319 to Silverman in view of U.S. Patent No. 5,462,062 to Rubinstein et al.

In reference to claims 17 and 18, Silverman discloses a method including piercing tissue with an instrument comprising an outer hollow cannula (10) and an inner member (14) having a distal end portion disposed within the hollow cannula; positioning the hollow cannula within the tissue at a desired tissue site (Col. 2, lines 4 – 6); actuating a first mechanism (15) associated with the instrument to move the distal end portion of the inner member distally (Col. 2, lines 6 – 9), relative to the outer cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted (Col. 2, lines 9 – 14); actuating a second mechanism (12) associated with the instrument to move the outer hollow cannula distally to retract the distal end portion (Col. 2, lines 14 – 19); and withdrawing the instrument and tissue sample from the tissue (Col. 2, lines 21 – 23). Silverman discloses the inner member being a needle and grasping a tissue sample with the distal end of the inner member (Col. 2, lines 16 - 18). However, Silverman fails to disclose using a plurality of hooked extractors associated with the distal end of the inner member. Rubinstein et al. discloses a method of extracting a tissue sample including the use of a pair of sharp-edged blades (44a, 44b) attached to hinges (42a, 42b) at opposite edges on the interior of a biopsy needle (Col. 3, lines 8 - 11). The inclusion of such a blade and hinge to each portion of the inner member disclosed by Silverman would form a pair of hooked extractors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal end of the needle

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disclosed by Silverman to include a pair of sharp-edged blades attached to hinges as taught by Rubinstein et al. in order to aid in severing the biopsy and retaining the biopsy in place as the inner member is removed from the patient (Col. 3, lines 11 – 17).

4. Claim 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,198,319 to Silverman in view of U.S. Patent No. 5,462,062 to Rubinstein et al. as applied above, and further in view of U.S. Patent No. 5,476,101 to Schramm et al.

In reference to claims 21 and 22, Silverman in view of Rubinstein et al. disclose manually actuating the first and second mechanisms. Schramm et al. teach a biopsy apparatus having a first (55) and second (56) spring element to store energy to drive an inner and outer cannula (Col. 6, lines 9 – 16). It would have been obvious to one having ordinary skill in the art to modify the device as disclosed by Silverman in view of Rubinstein et al. to include a first and second spring element to store energy to drive the outer hollow cannula and the inner member to allow for a more precise automated sampling procedure. Furthermore, the replacement of a manual operation with an automatic operation is a design consideration within the skill of the art. *In re Venner*, 262, F.2d 91, 120 USPQ 192 (CCPA1955).

Response to Arguments

5. Applicant's arguments filed 1/28/10 have been fully considered but they are not persuasive. Applicant asserts that Silverman teaches that the split portion of the inner needle should be divergent and spread apart as the needle is directed through the outer needle and into tissue, such that the split portion can encapsulate tissue and then be compressed together by the outer needle and that this is contrary to the use of a hinged blade of Rubinstein which is shown pointing radially inward in both Figures 3B and Figure 3D of Rubenstein. Also, Applicant asserts that the hinged blades of Rubenstein, if added to the interior needle of Silverman would close off the distal end of

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the interior needle as the inner needle is inserted through the outer needle of Silverman into tissue. However, the Examiner disagrees. Although the blades of Rubenstein partially occlude the opening of the needle, they are so designed to allow penetration into a tissue to receive a sufficient sized sample (See Figures 3A and 3C). Nonetheless, the inner needle of Silverman diverges, allowing for a larger sample. The addition of the blades of Rubenstein would not hinder the split portion of the inner needle of Silverman from diverging. The blades of Rubenstein are so designed to be folded upon insertion into the tissue (Figure 3A) and would actually aid in the diversion of the needle portions as a result of the distal angled face. Accordingly, the Examiner maintains that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal end of the needle disclosed by Silverman to include a pair of sharp-edged blades attached to hinges as taught by Rubinstein et al. in order to aid in severing the biopsy and retaining the biopsy in place as the inner member is removed from the patient (Col. 3, lines 11 – 17).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724.

The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736